

## **REMARKS**

### **Status of the Claims**

Claims 1, 3-8, 20, 21 and 23-34 are pending in the present application, and in the outstanding office action, all of the claims stand rejected. The only claim amendment made herein is to change the dependency of claim 34.

### **Introduction**

The invention claimed herein relates generally to suture welding systems and methods where a device for grasping sutures is provided with two electrodes connected to a source of electrosurgical energy so that the electrosurgical energy, generally radio frequency energy, can be passed through the sutures to weld them together. This application has been pending since December 18, 2001, there have been

- two restriction requirements (3/5/04, 11/28/05);
- two Examiners;
- four office actions (3/5/04, 11/2/04, 4/12/05, and 3/16/06) and an advisory action (1/26/05) rejecting all of the claims over prior art; and
- a telephonic interview.

All of this activity has taken place in this application despite the fact that no Examiner in any office action has cited any reference that provides electrodes connected to a source of electrosurgical energy to provide radio frequency energy to the sutures to weld them.

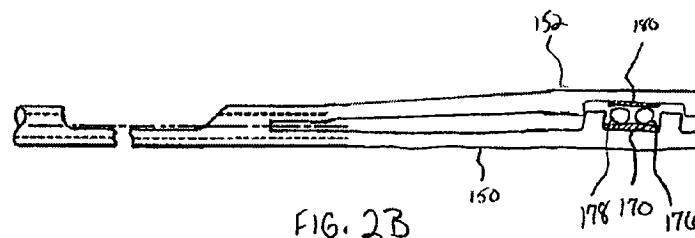
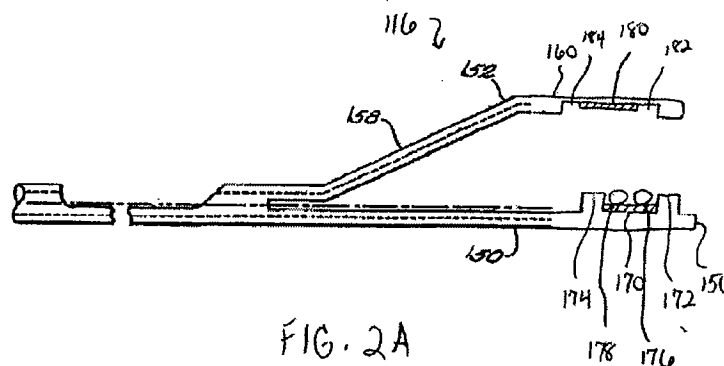
This lack of a basic teaching of the elements of the present invention continues in the outstanding final office action in which a new primary reference is applied that lacks the basic features of the invention.

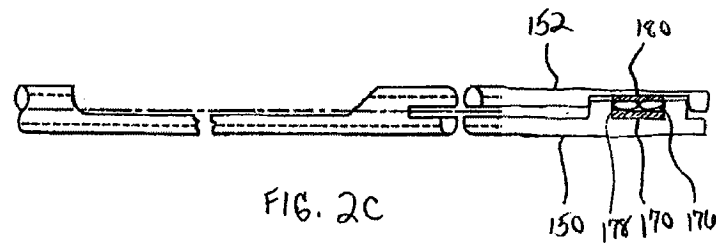
### **Applicants' Invention**

The present invention relates to systems, devices and methods for welding lengths of suture to create a fixed attachment between lengths of suture without tying knots. In general, the present invention provides a suture welding device having a suture contacting element with first

and second electrodes, and a source of electrosurgical energy coupled to the electrodes so that energy can be delivered to first and second lengths of suture in a manner that allows the lengths of suture to be welded to each other.

More specifically, a suture welding system of the invention includes an electrosurgical energy source and a suture welding device. The suture welding device has a working end as shown in FIGS. 2A-2C (reproduced below), a suture contacting element disposed on the working end, a first electrode 170 electrically coupled to the electrosurgical energy source, and a second electrode 180 electrically coupled to the electrosurgical energy source. The first electrode 170 is disposed on the suture contacting element for providing electrical energy to the first and second lengths of suture, and the second electrode 180 is disposable proximate to the suture welding site for providing a return electrical energy path to the electrosurgical energy source. When electrical energy is provided by the first electrode to the first and second lengths of suture, the first and second lengths of suture are welded into a fixed attachment.





In use, the suture grasper 116 is moved from an open position (FIG. 2A), to an intermediate position (FIG. 2B), and finally to a closed position (FIG. 2C). When the suture grasper 116 is fully closed and two lengths of suture 176, 178 are tightly held within the grasper 116, the lengths of suture 176, 178 can be deformed due to pressure applied to them by the electrodes 170, 180. With the first and second lengths of suture placed into contact with the suture contacting element, electrical energy from the electrosurgical energy source is provided through the first electrode to the first and second lengths of suture to weld the first length of suture to the second length of suture to create a fixed attachment therebetween.

With this overview of the invention in mind, the outstanding rejections will now be addressed.

#### **Rejection of Claim 7 Under 35 U.S.C. 112**

The Examiner states that claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner states:

Claim 7 recites the limitation of "a weldable material is provided between at least one electrode and at least one length of suture". This limitation suggests that there is an additional weldable material in addition to the "first and second lengths of suture" recited in the independent claim 1. However, it is unclear in the specification as to what constitutes as the third "weldable material". It appears to the Examiner that the limitations of claim 7 has in fact been previously amended to claim 1 in the recitation of "first and second lengths of suture". Therefore, it is suggested that claim 7 be cancelled to obviate the rejection under 112.

Quite to the contrary of the Examiner's assumption, the "weldable material" is provided in addition to the first and second lengths of suture. Further contrary to the Examiner's assumption, the specification is quite clear as to the nature of the weldable material as the application provides, at page 13, lines 1 to 11:

In addition to forming sutures from a weldable material, a separate ring or partial ring of weldable material could be provided in conjunction with the suture or with the suture welding device as illustrated in FIGS. 3 and 3A. As shown in FIG. 3, a suture grasper 116 is provided having electrodes 170, 180 where each electrode has a weldable material 186 preformed thereon. Upon heating, weldable material 186 preferably wicks onto sutures 176, 178 and melts around them to bond them together. Weldable material 186 may include a release layer formed adjacent to the electrodes to aid in the flow of the weldable material to the sutures. A further embodiment is illustrated in FIG. 3A in which weldable material 188 is formed as a ring or collar around sutures 176, 178. Upon heating by electrodes 170, 180, weldable material 188 melts around lengths of suture 176, 178 and thereby fixes the lengths of suture to each other.

Applicant submits that the specification is clear on this point and that the claims are clear as well.

**Rejection of Claims 1, 3, 4, 20, 21, 23-25 and 27-33 Under 35 U.S.C. 102**

The Examiner states that claims 1, 3, 4, 20, 21, 23-25 and 27-33 (including independent claims 1, 20, and 29) are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. 4,662,065 (Polonsky). Specifically, the Examiner states:

**Claim 1:**

As to claim 1, Polonsky teaches a suture welding system comprising an electrical energy source for producing radio frequency (RF) waves (col. 1, line 36); a first and second lengths of suture (the individual strands of suture beyond the knot seen in Fig. 6); a suture welding device comprising a working end (the jaws 20,22) having a suture contacting element (surface 28); a first electrode electrically coupled to the electrosurgical energy source and disposed on the suture contacting element (internally, col. 2, lines 33-37); and a second electrode electrically coupled to the electrical energy

source and disposed proximate the suture welding site for providing a return electrical energy path (the other surface 30); wherein the RF energy welds the suture together. As seen in Fig. 5, the electrodes within each jaw are coupled electrically to the energy source.

**Claims 20 and 21:**

As to claims 20 and 21, Polonsky teaches the method for welding sutures together, the method comprising providing an electrosurgical energy source (col. 1, line 36); providing a suture welding device comprising a working end (the jaws 20,22) having a suture contacting element (surface 28); a first electrode electrically coupled to the electrosurgical energy source and disposed on the suture contacting element (internally, col. 2, lines 33-37); and a second electrode electrically coupled to the electrical energy source and disposed proximate the suture welding site for providing a return electrical energy path (the other surface 30); placing a first and second length of suture into contact with the suture contracting element; a first and second lengths of suture (the individual strands of suture beyond the knot seen in Fig. 6); and providing RF energy to weld the sutures together.

**Claims 25, 28 and 29:**

As to claims 25, 28, and 29, Polonsky teaches at least one pod (58 or 60).

**Response to Anticipation Rejections of Independent Claims:**

The Polonsky reference cited by the Examiner as anticipating claim 1 suffers from the exact same flaws as the Morris reference that was cited in previous office actions – a reference that has been overcome. Namely, both the Polonsky and Morris references melt sutures by applying a heater. This is completely different from the claimed invention in which a first electrode provides radio frequency energy from an electrosurgical energy source to the first and second lengths of suture and a second electrode provides a return path for the energy to the electrosurgical energy source. This same issue has been addressed in previous amendments and in the telephonic interview, and applies with equal force to this newly cited, but same old disclosure, reference.

The Applicants' independent claim 1 recites a suture welding system that includes

- an *electrosurgical energy source configured to generate radio frequency waves*,
- first and second lengths of suture
- a suture welding device having a suture contacting element located on a working end
- a *first electrode providing radio frequency energy* to the first and second lengths of suture
- a *second electrode providing a return electrical energy path*
- wherein *provision of radio frequency energy* by a first electrode to the first and second lengths of suture *welds the first and second lengths of suture into a fixed attachment*.

As indicated above, Polonsky discloses a resistive heating element (actually, two resistive heating elements) used to heat and fuse strands of suture. While Polonsky discloses that fusing face may be “energized by a resistance heater or ultrasound<sup>1</sup> power source” (column 1, lines 34 to 36; the previously distinguished Morris reference also taught resistive heating or ultrasound), Polonsky fails to disclose, teach or suggest “an *electrosurgical energy source configured to generate radio frequency waves*,” as claimed by the Applicants.

Polonsky further fails to disclose, teach or suggest a *first electrode* electrically coupled to the source of electrosurgical energy *to provide radio frequency energy* to the first and second lengths of suture and a *second electrode* electrically coupled to the electrosurgical energy source *to provide a return electrical path*. The system of the claims thus creates an electrical circuit that provides radiofrequency energy from the electrosurgical energy source, through the first electrode, to the first and second lengths of suture, to the second electrode, and returning to the electrosurgical energy source. Polonsky discloses instead two parallel circuits for providing current to two resistive heaters (Figure 5, and column 2, lines to 24) found within the jaws of the

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<sup>1</sup> Ultrasound fusion is known in the art. See, e.g. U.S. Patent No. 6,358,271 to Egan that has been cited in previous office actions, and also page 1, lines 18 to 27 of the present application where ultrasonic welding is discussed in the background. Ultrasonic fusion works by vibrating the sutures to heat and fuse them. This is different from applying RF energy through electrodes forming an electrical circuit.

Polonsky device. There is no electrical circuit created through the first electrode, sutures, and second electrode as contemplated in the present claims.

Polonsky further fails to disclose, teach or suggest the *provision of radio frequency energy* by the first electrode to the first and second lengths of suture *to weld the first and second lengths of suture into a fixed attachment*. Rather, Polonsky only teaches fusion brought about by applying resistive heating to melt the sutures. (Column 2, lines 33 to 36.)

Each of these elements that are not taught by Polonsky are present in the system of claim 1 and the method of claim 20. Further, each element is present in the system of claim 29 (though recited as electrical energy rather than radio frequency energy) – and still not disclosed, taught or suggested by Polonsky.

**Rejection of Claims 5, 6, 26 and 34 Under 35 USC § 103**

The Examiner states that claims 5, 6, 26 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 4,662,065 (Polonsky) in view of U.S. 4,052,988 (Doddi). Specifically, the Examiner states:.

Polonsky is silent with regards to the material forming the suture. However, Doddi teaches a surgical suture that is made of polydioxanone, which provides desirable properties, such as improved strength, smoothness, and pliability. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to make Polonsky's' suture out of polydioxanone because this material has many surgically desirable properties such as tensile strength and pliability, as taught by Doddi.

Applicants' claims 6, 26 and 34 recite first and second lengths of suture that are made of polydioxanone.

In no way does Polonsky, either alone or in combination with Doddi, teach or suggest the recitations of Applicants' claims 6, 26 and 34. As noted above, Polonsky teaches fusion by resistive heating. Nowhere does Polonsky teach using electrodes to make a RF circuit through the suture material, as Polonsky has parallel resistive heaters. While Doddi discloses synthetic absorbable sutures and other surgical devices that are prepared from polymers of p-dioxanone and 1,4-dioxepan-2-one, and alkyl substituted derivatives thereof, *nowhere does Doddi disclose the welding of said sutures*. [Abstract.] Accordingly, even if Polonsky and Doddi could be

combined, the combination does not disclose all of the features of Applicants' claims 6, 26 and 34.

Further, there is no motivation to combine the Polonsky and Doddi references. The heating element in Polonsky is not capable of welding any and all suture materials, and there is no reason to believe that it would weld polydioxanone. Further, just because polydioxanone sutures are known does not mean that they can be welded. In fact, an express goal of the claimed invention, the first suture welding device of its type, is to employ radio frequency waves in order to facilitate the welding of polydioxanone sutures as the present inventors have found that existing suture welding methods did *not* work with polydioxanone sutures. (See, e.g., the background of the present invention at page 1, lines 22 to 31.) Accordingly, Applicants' claims 6, 26 and 34 is allowable over Morris in view of Doddi.

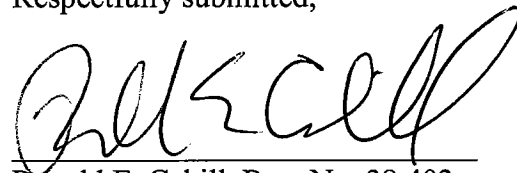


**CONCLUSION**

Applicants believe that the pending claims are in condition for allowance. If the Examiner believes that an interview would facilitate the resolution of any outstanding issues, he is kindly requested to contact the undersigned.

Dated: May 16, 2006

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Ronald E. Cahill', written over a horizontal line.

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